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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/636,519	08/10/2000	Jacques P. Dumas	5051	6414

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EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 11/18/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/636,519

Applicant(s)

DUMAS ET AL.

Examiner

Venkataraman Balasubramanian

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5,7-11,13-17 and 19-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-11,13-17 and 19-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicants' response, which included cancellation of claims 6, 12, 18, amendment to claims 1-3, 5, 7-9, 11, 13-15, 17, 19 and addition of new claims 20-25, filed on 8/29/2002, is made of record.

Claims 1-5, 7-11, 13-17, and 19-25 are now pending and are examined to the extent they embrace the elected subject matter ( See paper # 6).

In view of applicants' response, all 112 rejections made in the previous office action have been obviated.

In addition, prior art 102(e) rejection over Bold et al. is withdrawn.

However, the following apply.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 7-11, 13-17, and 20-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following apply. Any claim not specifically rejected is rejected as it dependent on a rejected claim.

1. Definition of G<sup>1</sup>, in claims 1-3, 7-9 and 13-15, renders these claims indefinite, as the Markush definition "selected form the group consisting of" embraced therein is improper. Note Such a Markush definition should have an "and" before the last choice. The same applies to G<sup>3</sup> and G<sup>4</sup> as well. An appropriate correction is needed.

2. In claims 1-3, 7-9 and 13-15, and other dependent claims, in Y definition, the value of p is missing and thereby renders these claims indefinite.
3. In claims 1-3, 7-9 and 13-15, and other dependent claims, recitation of the term "prodrug" is deemed as indefinite. Prodrugs in general and as noted in specification, are compounds, which undergo in vivo hydrolysis to parent active drugs. In that sense recitation of prodrug is acceptable. However, the definition of various variable on the phthalazine include such groups, namely esters, amides, alkoxycaronyl etc. and therefore it is not clear what is the difference between these variable groups and the prodrug groups. Hence the term renders these claims ambiguous and vague.
4. Recitation of "having a condition of tumor growth" in claims 5 and 11 renders these claims indefinite, as it is not clear what is intended. Note claim 6 and 12 recite, "wherein the said condition is tumor growth" thus it is not clear what is the condition.
5. Claims 6 and 12 also recite the term "including" which renders these claims indefinite. The transitional term "including," which is synonymous with or "comprising", "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. "Containing" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim "comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts". See MPEP 2111.03.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-11, 13-17, and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bold et al. US 6,258,812 (or equivalent WO 98/35958)

Bold et al. teaches several phthalazines with angiogenesis activity, which include compounds claimed in the instant claims. See formula I on col. 3 and note the definition of various groups. Note the definition of N-containing A-B-D-E ring corresponds to instant A-B-D-E-L ring, Q corresponds to instant G<sup>3</sup>, G corresponds to instant Y, X corresponds to instant J. Particularly note when Y is aryl the substituents permitted includes those claimed in the instant claims for G<sup>4</sup> group. See col. 4 through col. 17 for details and preferred embodiments and col. 18-34 for process of making these compounds. Also see col. 34-81 for examples of compounds made including the tables shown therein.

The instant claims differ from the reference in requiring variously substituted compounds with substituents in the phthalazine ring, heterocyclic ring A-B-D-E-L ring, and J ring. Furthermore, claim 19 requires specific species. Bold et al. as noted in examples shown on col. 34-81 teaches variously substituted phthalazines but does not exemplify all compounds claimed.

However, Bold et al. teaches the equivalency of exemplified substituted phthalazines shown in examples and the tables stated above with phthalazines with variously substituted in aryl ring, N-A-B-D-E ring and the aryl ring of the phthalazine ring claimed in the definition of compound of formula I. See cols. 1 through col. 17. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made would have been to make compounds variously substituted phthalazine and aryl and N-A-B-D-E rings as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

This rejection is similar to that made in the previous office action. Applicants' argument to overcome this rejection is not persuasive. Contrary to applicants' urging that instant Y, G<sup>3</sup> and G<sup>4</sup> are not obvious over the cited prior art, as noted above the definition of these groups overlap with corresponding groups recited in the said prior art and in view of the equivalency teaching, the instant invention is obvious variant of the over the prior art.

Claims 1-5, 7-11, 13-17, and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watanabe et al. EP 0 722 936.

Watanabe et al. teaches several fused pyridazine compounds useful for treating cGMP-PDE inhibitors for treating several heart diseases and asthma, which include compounds generically claimed in the instant claims. See formula I on page 2 and note the definition of A, X, Y, R<sup>1</sup> and n.

Note when X is N, the core is phthalazine and is same as the instant core of elected subject matter (See paper # 6). Note the definition of  $R^1$  corresponds to instant  $G^1$  and has overlapping groups. Note the definition of B (when Y of the reference is C-B) corresponds to instant Y. Especially note the definition of B permits substituents on the alkyl, which overlaps with those of instant  $G^2$ . See pages 3-6 for preferred embodiments, pages 7-11 for process of making. See examples 1-73 on pages 15-57 for compounds made.

The instant claims differ from the reference in requiring variously substituted compounds with substituents in the phthalazine ring, heterocyclic ring A-B-D-E-L ring, and J ring. Furthermore, claim 19 requires specific species.

Watanabe et al. as noted in examples 1-73 on pages 15-57, teaches variously substituted phthalazines but does not exemplify all compounds generically claimed.

However, Watanabe et al. teaches the equivalency of exemplified substituted phthalazines shown in examples stated above with phthalazines with variously substituted with A, B and in the aryl ring of the phthalazine ring claimed in the definition of compound of formula I. See pages 1-6. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made would have been to make compounds variously substituted phthalazine as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

This action is not made FINAL.

References cited in the Information Disclosure Statement (paper # 8) are made of record.

***Conclusion***

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (703) 308-4716.

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

*V. Balasubramanian*  
Venkataraman Balasubramanian

11/15/2002